Helmling et al.

Response to Final Office Action mailed 11 May 2009

Atty. Docket No.: 021315-08220400

REMARKS

I. Regarding claim 24, the first full paragraph on page 2 of the instant application

teaches that an antagonist of interest reduces ghrelin activity (is a ghrelin antagonist) and reduces

GHSR 1a activity (is a GHSR 1a antagonist); the paragraph bridging pages 1 and 2 teaches the

functions associated with a ghrelin or a GHSR 1a; and in the paragraph bridging pages 13 and 14

teaches the need and/or benefit of reducing ghrelin or GHSR 1a function in certain conditions.

Regarding claim 29, the first full paragraph of page 15 teaches competition assays to find ghrelin

antagonists, using assays known in the art, wherein, for example, ghrelin is labeled.

Accordingly, no issue of new matter arises with the above amendments, the amendments place

the claims in condition for allowance and at the least, the amendments simplify issues for appeal.

Hence, entry of the amendments is requested respectfully.

II. At the lower half of page 2 of the Office Action, the Examiner raised an objection

to claims 2, 6, 12, 13 and 31-36 alleging that the claims were essentially duplicates of an allowed

claim. Claims 14 and 37-41 were alleged not to limit further a prior claim.

The objection is traversed for the following reasons.

A nucleic acid which has the sequence of SEO ID NO:8 as recited in claim 1 is one

which contains at least SEQ ID NO:8, see, for example, the last full paragraph on page 8, the

third full paragraph on page 11, the paragraph bridging pages 14 and 15, Examples 3 and 4, and

Figures 22-25, which teach that the nucleic acid of interest can contain, for example, flanking

sequences and retain the desired activity.

Hence, a nucleic acid of interest can bind to different molecules, can have varying overall

structure and can have varying properties without deviating from the function of SEQ ID NO:8.

that is, antagonizing ghrelin or GHSR Ia function, for example, by having varying length or

varying affinity levels for a ligand.

In any event, to advance prosecution and to place the instant application in condition for

allowance, applicants canceled claims 2, 12-14 and 31-41 without prejudice to prosecution in a

continuation application. Claim 6 was amended to further define the ghrelin structure.

Accordingly, the objection can be withdrawn.

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III. At the bottom of page 4 of the Office Action, claims 16-18, 20-22 and 29 were

rejected under 35 U.S.C. 112, second paragraph.

The rejection is traversed for the following reasons.

Claims 16 and 20 recite methods to obtain the nucleic acid of claim 1. Claim 29 relates

to a competition assay, essentially as known in the art. Hence, the antagonist of claim 1 can be

used to locate other molecules which also antagonize ghrelin or GHSR 1a function in a

competition assay.

In view of the claim amendments, withdrawal of the rejection is in order.

IV. At the top of page 6 of the Office Action, claims 24 and 25 were rejected under

35 U.S.C. 112, first paragraph for an alleged want of enablement.

The rejection is traversed for the following reasons.

The instant specification teaches ghrelin regulating, for example, appetite, see paragraph

bridging pages 1 and 2. Examples 8, 9 and 12 show the expected in vivo effect of an antagonist

of interest. Example 11 shows a reduction in growth hormone release on expression of an

antagonist of interest.

The molecule of interest can be configured to be stable to naturally occurring nucleases.

for example, by containing an L-base. Hence, a molecule of interest will have enhanced plasma

half life.

Submitted herewith is a copy of Shearman et al., Endo 147(3):1517-1526, 2006, which

reports on studies conducted using antagonists of interest. As provided in the instant

specification, the antagonists of Shearman et al. blocked ghrelin-induced feeding, promoted

weight loss and reduced fat mass.

Accordingly, the antagonist of interest functions as taught in the instant specification

in vitro and in vivo. The instant specification teaches how to make and how to use the invention

of interest.

As noted on page 1523, right column, first full paragraph of Shearman et al., another

study using ghrelin knockout mice observed the opposite phenotype as reported in Sun et al. of

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record. Hence, the working examples of the instant specification and Shearman et al. support the claimed invention.

In view thereof, the instant specification enables the claimed invention. Accordingly, the rejection can be removed.

V. Claims 1, 27 and 45 were allowed. Claims 3, 4, 9-11, 26 and 30 are allowable if rewritten in independent form including limitations of the base claim and any intervening claims.

Claims 3, 4, 26 and 30 depend on allowed claim 1. Claims 9 and 10 were canceled without prejudice. Claim 6 was amended to exemplify an element.

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CONCLUSION

Applicants have taken steps to place the instant application in condition for allowance. Reexamination, reconsideration, withdrawal of the objection and rejections, and early indication of allowance are solicited earnestly.

Respectfully submitted,

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